TESTIMONY BEFORE THE

HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

ON

SAFE AND AFFORDABLE BIOTECH DRUGS—THE NEED FOR A GENERIC PATHWAY

March 26, 2006

WASHINGTON, D. C.

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Mr. Chairman and members of the Committee, I am Nelda Barnett, a member of AARP's Board of Directors. AARP appreciates the opportunity to testify today in support of creating a pathway for generic biologics. Older Americans use prescription drugs more than any other segment of the U.S. population, and as a result, AARP is deeply committed to providing our members – and all Americans – access to safe, affordable prescription medications.

Modern medicine increasingly relies on prescription medications. These prescription medications can come in many forms – such as traditional prescription drugs (small molecule compounds that are chemically manufactured), and the increasingly-used biological products (a more complex drug that is typically derived from a living source). The Hatch-Waxman Act of 1984 created a pathway for the Food and Drug Administration (FDA) to approve generic versions of traditional prescription drugs. Currently, there exists no similar process at the FDA for the approval of generic biological products.

AARP has endorsed the Access to Life-Saving Medicine Act (H.R. 1038) because we believe this legislation will create a much needed pathway for the approval of safe, comparable, and interchangeable versions of biologics. We call on Congress to pass the legislation this year.

One woman's story

Nothing illustrates how important it is that we have a pathway to lower cost generic versions than the stories of those Americans who currently cannot afford high priced biologic drugs.

One of my colleagues on AARP's Board of Directors has asked that I share with you her particular story. Bonnie suffers from severe rheumatoid arthritis and, over the years, has undergone a variety of treatment options. Like any patient she researched her disease and had extensive conversations with her doctor

about possible treatment options. Her research led her to the biologic drug, Enbrel. Because all other forms of treatment had failed, she was fortunate to have her insurance cover this biologic drug.

Shortly after beginning to take the biologic, Bonnie had no sign of the disease and was able to work and enjoy life in a way she had not done for over 30 years. Having access to this drug has made a miraculous difference in Bonnie's health and well-being. But not everyone has been so lucky. Bonnie has encountered many people who suffer from the same condition who are not able to afford the biologic medication. One particular woman was so affected by the disease that her fingers were gnarled, she had difficulty walking, and like many who suffer from chronic illness, she used all her energy just to get through a day. This woman recounted how she was trying to find a way to get access to Enbrel. Like Bonnie, she had gone through every possible treatment option, but unfortunately wasn't getting any better – and in fact was getting worse. She had read about this new drug, but there was no way that she could afford the drug.

Bonnie tells it best in her own words: "Having lived with this disease for 40 years, I know how incapacitating it can be and how the pain can be unbearable. You watch, in disbelief, as you grow more and more physically incapacitated day by day. I know what hope biologics can give to someone whose whole life is affected. I know how it can affect a person's life. To know that it cannot be obtained by other people with deadly diseases is brutal. How do you tell someone that they cannot have a treatment that may alter their lives significantly?"

Consumers need access to safe and effective generic biologics.

Use of biologic drugs is increasing every year[1] to treat diseases and conditions such as cancer, multiple sclerosis, anemia, and rheumatoid arthritis. Research and development into this vital field is growing – there are currently hundreds of applications in the pipeline. These treatment therapies are, in many cases, truly cutting edge technology. For someone like Bonnie who has rheumatoid arthritis, her biologic treatment therapy made the difference between having the ability to walk and having to live with debilitating, constant pain.

While biologics hold great promise for treating some of the most serious diseases, these treatment regimens can be very expensive. Some treatments can cost tens of thousands of dollars per month or hundreds of thousands of dollars per year. For example, Epogen, a drug used to treat anemia, can cost as much as $10,000 per year. Cerezyne, used to treat Gaucher disease, can cost as much as $200,000 per year – which is almost as much as the average price of a home in January 2007.[2] Similarly, a person diagnosed with colon cancer may be prescribed Avastin, which can cost $100,000 per year, more than the average cost of a four-year college education.[3]

Some individuals are fortunate enough to have insurance coverage and/or the means to be able to afford these medications. However many are not so lucky. The astronomical cost of biologics not only impacts consumers, but also health care payers such as employers, private health care plans, and public programs like Medicare and Medicaid. In fact, spending on biologic drugs continues to

[1] Biotech Drugs Come of Age; Policymakers Take Note, Health Affairs, Sept./Oct. 2006 (reporting that in 2005 revenues for biological drugs totaled $50.7 billion, an increase of 15.8 percent over 2004).
[2] National Association of Realtors data, available at http://www.realtor.org/research/index.html (reporting the existing home median price was $210,000 in January 2007).
[3] College Board, Trends in College Pricing 2006, available at http://www.collegeboard.com/prod_downloads/press/cost06/trends_college_pricing_06.pdf (reporting that average total tuition and fees at a four-year private college or university for the 2006-2007 academic year was $22,218).

outpace even that of traditional brand name prescription drugs,[4] whose cost increases – at twice the level of inflation – are also too high.[5] One way to control these costs is to provide a pathway for the approval of generic versions of these products. A recent study by a large pharmacy benefit manager estimated a savings of $71 billion over ten years to the entire health care system if the FDA approved a pathway for generic biologics in just four therapeutic areas: interferons for multiple sclerosis; erythropoietin for anemia; growth hormone for growth failure; and insulin for diabetes.[6]

History tells us that lower priced drugs can be brought to market safely and effectively. As a result of the Hatch-Waxman Act, today, generic prescription drugs save consumers and health care payers billions of dollars each year.[7] Approximately 56 percent of all prescriptions filled in the U.S. – more than one billion prescriptions every year – are lower-cost generic prescription drugs.[8]

Those who oppose creating a pathway for the FDA to approve generic biologic drugs have claimed that lowering prices would hinder research and development efforts. This argument, similar to opposition claims at the time Hatch-Waxman was enacted, again rings hollow. In 1984, critics claimed that as a result of generic prescription drugs, consumers would suffer because companies would no longer invest resources to find new cures. History has proven these critics wrong. More consumers than ever have access to more affordable generic

[4] Elise Wang, et. al, A Global "Generic Biologics" Guidebook, Citigroup, Nov. 6, 2006, pg. 30.
[5] David J. Gross, Leigh Gross Purvis, and Stephen W. Schondelmeyer, *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2006 Year-End Update*, AARP Public Policy Institute Data Digest #DD154 (Washington, DC: AARP), March 2007 (finding that on average, pharmaceutical manufacturer prices for the 193 brand name drugs most widely used by older Americans rose at nearly twice the rate of general inflation in 2006).
[6] Express Scripts, Financial Impact of Biogenerics, March 16, 2007.
[7] CBO, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998.
[8] Statistics from the Generic Pharmaceutical Association (Available online at: http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm).

drugs. And the pharmaceutical industry – now the fifth most profitable industry in the country[9] – has been hugely profitable.

Legislation ensures safety and access.

Any prescription drug treatment therapy regimen must be affordable and safe in order to be effective for individuals. Generic versions of biologics will produce lower cost alternative treatment therapies, but these treatment therapies must also be safe in order to be effective.

While biologics are more complex than traditional prescription drugs, complexity alone is not a valid reason to prevent research into the development of generic versions. Technology has progressed to the point where biologics are better understood and characterized – a statement we could not have made when the Hatch-Waxman Act was passed in 1984. As a result, it is now possible to create generic versions of these treatment therapies.

The Access to Life-Saving Medicines Act grants FDA the authority to create a pathway for the generic approval of biologics. The legislation does not mandate that the FDA approve a certain number of applications – only that FDA provide for the pathway of approval. And the legislation leaves the scientific determinations up to those who are best equipped to address them – the FDA. Common sense alone tells us that the agency that has the scientific knowledge to approve a brand-name biologic surely has the ability to provide a pathway for generic approval of the same biologic.

As science advances, we can expect prescription drugs to become an increasingly important component of health care, and for biologic drugs to become a larger component of drug spending. When brand name prescription drugs go off patent, a generic manufacturer can begin marketing its lower cost

[9] Fortune 500 2006, "Most Profitable Industries: Return on Revenue," April 17, 2006.

alternative after being approved by the FDA. The time is now to create such a pathway for biologics. Today, manufacturers continue to reap the rewards of their patent long after its expiration. As a result, consumers continue to pay high prices for biologics, and it costs the health care system billions of dollars more.

It is critical not only for individuals, but for all health payers – including federal and state governments, employers and insurers – that we begin to take steps to lower the cost of these biologics. The Hatch-Waxman Act created an abbreviated pathway for the approval of generic drug applications, and consumer and health care payers benefited. Now Congress has the opportunity to pass the Access to Life-Saving Medicines Act, which gives the FDA the authority to approve generic versions of biologics. Once this legislation has been enacted, consumers and health care payers can begin to see savings on these life saving medications.

Conclusion

The Hatch-Waxman Act created a pathway for FDA to approve generic prescription drugs. Twenty-three years later, the time has come for generic approval of biologics. The Access to Life-Saving Medicines Act provides FDA the authority to produce a safe, comparable or interchangeable version of a biologic, and scientific advancements now ensure FDA has the ability to approve generics safely.

Our members, and all Americans, need Congress to enact this bi-partisan legislation this year. We are pleased to see this Committee, and Members from both Houses of Congress and both sides of the aisle, moving forward on this issue.